510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
K031898

B. Analyte:
Hemoglobin

C. Type of Test:
Quantitative, Photometric Measurement

D. Applicant:
EKF Diagnostic

E. Proprietary and Established Names:
Hemo_Control Hemoglobin Measurement System

F. Regulatory Information:

1. Regulation section:
   21CFR 864.5620
2. Classification:
   Class II
3. Product Code:
   GKR
4. Panel:
   Hematology (81)

G. Intended Use:

1. Indication(s) for use:
   The Hemo_Control is indicated for the quantitative determination of hemoglobin in arterial, venous, and capillary whole blood in adults, infants, and children in a professional point-of-care setting.
2. Special condition for use statement(s):

3. Special instrument Requirements:

H. Device Description:
The Hemo_Control system consists of a photometer and individual single-use microcuvettes filled with reagents.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   HemoCue B-Hemoglobin System
   Careside Hemoglobin
2. Predicate K number(s):
   K973161
   K001462
3. Comparison with predicate:

Similarities			
Item	**Device**	**Predicate 1**	**Predicate 2**
Intended use	Quantitative determination of hemoglobin	Same	Same
Sample requirements	Venous, capillary, or arterial blood	Same	Same
Methodology	Hem-Azide methemoglobin Hct-Estimation from hemoglobin	Hgb- Same Hct-none	Hgb- none Hct -same
Differences			
Item	**Device**	**Predicate 1**	
Data Handling Features	Time/Date Logging Data Storage Capability	Some models Some models	

J. Standard/Guidance Document Referenced (if applicable):

EN 60601-1 (03/96) Medical Electrical Equipment Part 1. General Requirements for Safety

EN 60601-1-2 (09/94) Medical Electrical Equipment Collateral Standard. Electromagnetic Compatibility Requirements & Tests

H15-A3 Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard- Third Edition, NCCLS

AAMI/ISO 14971 Medical Devices: Application of Risk Management to Medical Devices

93/42/EEC EU Law for Medical Products, device according to class IIa

HHS (FDA) 97-4224 In Vitro Diagnostic Devices: Guidance for the Preparation of 510(k) Submissions, January 1997

Guidance for FDA Staff – Regulating In Vitro Diagnostic Device (IVD) Studies, December 17, 1999

FDA Guidance Document-Reviewer Guidance for Premarket Notification Submissions, Portions applicable to Electromagnetic compatibility, Nov. 1993

Guidance for Industry: Acceptance of Foreign Clinical Studies, March 2001

Guidance for FDA Staff: Regulation of In Vitro Diagnostic Device Studies, Dec 17, 1999

K. Test Principle:

The device uses an azide methemoglobin method to measure hemoglobin.

A small amount of blood is loaded into the microcuvette via capillary action. The cuvette is then inserted into the Hemo_Control photometer where the color produced by the chemical reaction in the cuvette is measured. Results are displayed by LED readout.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

	With-in Run (CV)	Total (CV)	Single Observation 20 days (CV)
Hemoglobin/Low (107 g/L)	0.8%	1.0%	0.9%
Hemoglobin/Normal (129 g/L)	0.6%	1.0%	0.8%
Hemoglobin/High (173 g/L)	0.6%	1.1%	1.0%

b. Linearity/assay reportable range:
0-25.6 g/dL

c. Traceability (controls, calibrators, or method):
Device calibrated against NCCLS reference method

d. Detection limit:

e. Analytical specificity:

f. Assay cut-off:

2. Comparison studies:

a. Method comparison with predicate device:

Comparison to NCCLS Reference Method:
y=1.0064X +0.0234, r=0.0076, n=174

Comparison to predicate (HemoCue)
y=1.0005x-0.2334, r=0.9962, n=286

Comparison of Hemo_Control Cuvettes in HemoCue to predicate (HemoCue)
y=.9855x+0.139, r=0.998, n=286

b. Matrix comparison:

Capillary Samples, 4 sites:

y=0.96x + 0.3742, r=0.8256, n=275,

Arterial Samples, 1 site:

y =0.9868x – 0.0285, r =0.998, n=10

3. Clinical studies:
    a. *Clinical sensitivity:*

    b. *Clinical specificity:*

    c. *Other clinical supportive data (when a and b is not applicable):*

4. Clinical cut-off:

5. Expected values/Reference range:

Based on literature references

Women: 12.0 – 16.0 g/dl
Men: 13.0 – 17.5 g/dl
Children, depending on age: 9.0 -24 g/dl

M. Conclusion:

Performance data has demonstrated that this device is substantially equivalent to a legally marketed device.